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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

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ORTHO BIOTECH PRODUCTS, L.P.,	:	
	:	
Plaintiff,	:	
	:	Civ. No.: 05-cv-4850-SRC-JJH
- v. -	:	
	:	
AMGEN INC.,	:	
	:	
Defendant.	:	
	:	
-----X	:	

**DEFENDANT'S MEMORANDUM IN OPPOSITION TO
MOTION FOR EXPEDITED DISCOVERY**

TABLE OF CONTENTS

	Page
PRELIMINARY STATEMENT	1
STATEMENT OF FACTS.....	3
1. Aranesp® Was An Innovative Breakthrough, Beneficial To Patients In Need Of RBCGF.....	4
2. Customers Are Neither Contractually Nor Economically Compelled To Buy Aranesp®	5
3. Revisions To Amgen’s Discount Program, Effective October 1, 2005, Modify Amgen’s Nearly Two-Year-Old Discount Program	7
4. Oncology Clinics Are Only One Type Of RBCGF Customer.....	7
5. Ortho/J&J, Which Had An Eleven Year Monopoly In RBCGF, Currently Has Approximately 50% Market Share Of The RBCGF Market.....	8
6. Ortho/J&J Has Numerous Options For Competing With Amgen	8
7. Ortho/J&J Can Profitably Discount Prices To Oncology Clinics.....	9
8. Amgen’s Discount Program Is A Defensive Move In Response To The Many Competitive Advantages Of Procrit®	9
ARGUMENT	10
I. ORTHO/J&J’S MOTION FOR EXPEDITED DISCOVERY SHOULD BE DENIED	10
A. Ortho/J&J's Alleged Harm Is Not Irreparable, And Is Fully Compensable By Money Damages.....	10
1. Ortho/J&J’s Alleged Harm Is Compensable And Calculable	11
2. Ortho/J&J Cites No Case In Which Irreparable Harm Was Found Under Even Remotely Analogous Facts or Legal Claims	13
B. Ortho/J&J Has Substantial Marketing Resources, And Amgen’s Discount Program Does Not Result In Any Significant Foreclosure.....	14
C. Entry Of A Preliminary Injunction would Alter The Status Quo, And Would Likely Harm Customers And Patients.....	15

TABLE OF CONTENTS

(continued)

	Page
D. Ortho's Claims Present Complex Factual and Legal Issues Which are Likely to be Resolved against Ortho/J&J	16
1. Ortho/J&J Has Failed To Allege a Proper Relevant Antitrust Market.....	16
2. The Discounting About Which Ortho/J&J Complains Does Not Constitute Tying In Violation Of Section 1 Of The Sherman Act	18
3. Amgen's Discounting Program is not Attempted Monopolization	20
II. ORTHO/J&J'S CLAIMS SHOULD BE RESOLVED ON A FULLY DEVELOPED RECORD	22
A. There Is No Case Law Supporting The Relief Ortho/J&J Seeks	23
1. Analogous Cases Have Not Been Subject To A Preliminary Injunction.....	23
2. Cases Cited by Ortho/J&J Where Expedited Discovery Was Ordered Are Not Analogous To The Present Case	24
B. Ortho/J&J's Proposed Schedule Provides Insufficient Time To Complete Discovery Necessary To Properly Adjudicate Ortho/J&J's Claims.....	25
1. Ortho/J&J's Proposed Schedule Allows Too Little Time For Amgen to Fully Comply with Ortho/J&J's Discovery Requests.....	25
2. Ortho/J&J's Proposed Schedule Allows Too Little Time For Amgen Properly To Conduct Its Own Discovery.....	25
3. Ortho/J&J's Proposed Schedule Provides Too Little Time To Generate An Adequate Economic Analysis	25
C. Full Discovery Is Necessary To Appropriately Resolve These Complex Legal and Factual Issues	26
CONCLUSION	28

TABLE OF AUTHORITIES

Cases

<i>Acierno v. Mitchell</i> , 6 F.3d 970 (3d Cir. 1993)	24
<i>Acierno v. New Castle County</i> , 40 F.3d 645 (3d Cir. 1994).....	11
<i>ACLU v. Reno</i> , 217 F.3d 162 (3d Cir. 2000).....	23
<i>Alberta Gas Chems., Ltd. v. E. I. duPont de Nemours & Co.</i> , 826 F.2d 1235 (3d Cir. 1987).....	21
<i>Alcatel Space, S.A. v. Loral Space & Communs. Ltd.</i> , 154 F. Supp. 2d 570 (S.D.N.Y. 2001).....	23
<i>Allen-Myland, Inc. v. Int'l Bus. Machines Corp.</i> , 33 F.3d 194 (3d Cir. 1994)	24
<i>Allis-Chalmers Mfg. Co. v. White Consol. Indus., Inc.</i> , 414 F.2d 506 (3d Cir. 1969).....	24
<i>Barr Labs., Inc. v. Abbott Labs.</i> , 978 F.2d 98 (3d Cir. 1992)	21
<i>Barr Labs., Inc. v. Abbott Labs.</i> , No. 87-4764, 1991 U.S. Dist. LEXIS 17690 (D.N.J. Nov. 29, 1991).....	16, 17
<i>Barre-National, Inc. v. Doshi</i> , No. Civ. 88-1847, 1988 WL 36335 (D.N.J. Apr. 18, 1988).....	24
<i>Bascom Food Prods. Corp. v. Reese Finer Foods, Inc.</i> , 715 F. Supp. 616 (D.N.J. 1989)	13
<i>Bogosian v. Gulf Oil Corp.</i> , 561 F.2d 434 (3d Cir. 1977)	19
<i>Bogosian v. Gulf Oil Corp.</i> , 596 F. Supp. 62 (E.D. Pa. 1984)	20
<i>Bristol Tech., Inc. v. Microsoft Corp.</i> , 42 F. Supp. 2d 153 (D.Conn. 1998).....	13
<i>Brooke Group, Ltd. v. Brown & Williamson Tobacco Corp.</i> , 509 U.S. 209 (1993)	16
<i>Brown Shoe Co. v. United States</i> , 370 U.S. 294 (1962)	18
<i>Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.</i> , 429 U.S. 477 (1977).....	22
<i>C&A Carbone, Inc. v. Clarkstown</i> , 770 F. Supp. 848 (S.D.N.Y. 1991).....	14
<i>Capital City Publ'g Co. v. Trenton Times Corp.</i> , 575 F. Supp. 1339 (D.N.J. 1983)	24
<i>Cargill, Inc. v. Monfort</i> , 479 U.S. 104 (1986).....	22

<i>Cent. Jersey Freightliner, Inc. v. Freightliner Corp.</i> , 987 F. Supp. 289 (D.N.J. 1997)	11, 12, 24
<i>Columbia Metal Culvert Co. v. Kaiser Aluminum & Chem. Corp.</i> , 579 F.2d 20 (3d Cir. 1978)	16, 17
<i>ECRI v. McGraw-Hill, Inc.</i> , 809 F.2d 223 (3d Cir. 1987)	23
<i>Frank's GMC Truck Center, Inc. v. Gen. Motors Corp.</i> , 847 F.2d 100 (3d Cir. 1988)	10
<i>Glasco v. Hills</i> , 558 F.2d 179 (3d Cir. 1977)	12
<i>Glaxosmithkline Consumer Healthcare, L.P. v. Merix Pharm. Corp.</i> , No. Civ. 05-898, 2005 WL 2230318 (D.N.J. Sept. 13, 2005)	24
<i>Highmark, Inc. v. UPMC Health Plan, Inc.</i> , 276 F.3d 160 (3d Cir. 2001)	23
<i>Hohe v. Casey</i> , 868 F.2d 69 (3d Cir. 1989)	11
<i>In re Arthur Treacher's Franchisee Litig.</i> , 689 F.2d 1137 (3d Cir. 1982)	23
<i>Instant Air Freight Co. v. C.F. Air Freight Inc.</i> , 882 F.2d 797 (3d Cir. 1989)	12
<i>J&M Turner, Inc. v. Applied Bolting Tech. Prods. Inc.</i> , Nos. 95-2179, 96-5819, 1997 U.S. Dist. LEXIS 1835 (E.D. Pa. Feb. 20, 1997)	11
<i>Jefferson Parish Hospital Dist. No. 2 v. Hyde</i> , 466 U.S. 2 (1984)	19
<i>Kellam Energy, Inc. v. Duncan</i> , 668 F. Supp. 861 (D. Del. 1987)	19, 20
<i>Kinetic Concepts, Inc. v. Hillenbrand Indus., Inc.</i> , 262 F. Supp. 2d 722 (Docket No. 95-CV-755)	23, 26
<i>LePage's, Inc. v. 3M</i> , No. 97-3983, 2000 U.S. Dist. LEXIS 3087 (E.D. Pa. Mar. 14, 2000)	23
<i>Lockheed Martin Corp. v. Boeing Co.</i> , 314 F. Supp. 2d 1198 (M.D. Fla. 2004)	18
<i>Masimo Corp. v. Tyco Health Care, et al.</i> , 2:02-cv-04770 (C.D. Cal. Filed May 22, 2002)	23, 26
<i>N. Pac. Ry. v. United States</i> , 356 U.S. 1 (1958)	18
<i>NCAA v. Board of Regents</i> , 468 U.S. 85 (1984)	20
<i>Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.</i> , 290 F.3d 578 (3d Cir. 2002)	13

<i>Ortho Diagnostic Sys. v. Abbott Labs.</i> , 920 F. Supp. 455 (S.D.N.Y. 1996)	12, 26
<i>Ortho Diagnostic Sys., Inc. v. Abbott Labs., Inc.</i> , 822 F. Supp. 145 (S.D.N.Y. 1993)	10, 12, 15, 23
<i>Pa. Dental Ass'n v. Med. Serv. Ass'n</i> , 745 F.2d 248 (3d Cir. 1984)	17
<i>Pappan Enters., Inc. v. Hardee's Food Sys.</i> , 143 F.3d 800 (3d Cir. 1998)	14
<i>PepsiCo, Inc. v. Coca-Cola Co.</i> , 315 F.3d 101 (2d Cir. 2002)	17
<i>Sampson v. Murray</i> , 415 U.S. 61 (1974)	11
<i>SmithKline Corp. v. Eli Lilly & Co.</i> , 575 F.2d 1056 (3d Cir. 1978)	17
<i>SmithKline v. Eli Lilly & Co.</i> , 427 F. Supp. 1089 (E.D. Pa. 1976)	23
<i>Spectrum Sports, Inc. v. McQuillan</i> , 506 U.S. 447 (1993)	21
<i>Structure Probe, Inc. v. Franklin Inst.</i> , 450 F. Supp. 1272, n.16 (E.D. Pa. 1978)	21
<i>Syncsort Inc. v. Sequential Software, Inc.</i> , 50 F. Supp. 2d 318 (D.N.J. 1999)	17
<i>Times-Picayune Publ'g Co. v. United States</i> , 345 U.S. 594 (1953)	21, 22
<i>TKR Cable Co. v. Cable City Corp.</i> , 267 F.3d 196 (3d Cir. 2001)	24
<i>Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.</i> , 959 F.2d 468 (3d Cir. 1992)	20
<i>Tully v. Mott Supermarkets, Inc.</i> , 337 F. Supp. 834 (D.N.J. 1972)	13
<i>United States v. E. I. Du Pont de Nemours & Co.</i> , 351 U.S. 377 (1956)	17
<i>Ways & Means, Inc. v. IVAC Corp.</i> , 506 F. Supp. 697 (N.D. Cal. 1979)	19
<i>Yong Ki Hong v. KBS Am., Inc.</i> , No. 05-CV-1177, 2005 WL 1712236 (E.D.N.Y. Jul. 22, 2005)	13
<i>Zenith Radio Corp. v. Hazeltine Research, Inc.</i> , 395 U.S. 100 (1969)	23

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10 Areeda & Hovenkamp, Antitrust Law, ¶ 1758b, 327 (2d ed. 2005)	19
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PRELIMINARY STATEMENT

The plaintiff in this case, Ortho Biotech Products L.P., (“Ortho/J&J”), an operating company owned by Johnson and Johnson, Inc., a company with a market value of almost \$200 billion, alleges that it is unable to compete in its efforts to sell a pharmaceutical product that is very profitable and accounts for approximately 50% of non-dialysis red blood cell growth factor (“RBCGF”) sales. Its attempts to obtain an immediate preliminary injunction and the proposed expedited discovery are without factual or legal justification, are unfair and should be denied.

To begin with, this is not a typical antitrust case, if it is a valid antitrust case at all. The plaintiff is a former monopolist, which until three years ago accounted for nearly 100% of non-dialysis RBCGF sales, and is now seeking to use the Sherman Act to protect its significant market position. Even at this most basic level, a healthy dose of skepticism is appropriate.

The supposed “recent” development that Ortho/J&J contends entitles it to an immediate injunction is nothing more than a modification of an Amgen USA Inc.¹ (“Amgen”) program, the essential structure of which Ortho/J&J admits has been in place since Spring 2004. The only “irreparable” harm that Ortho/J&J can identify from the lack of an injunction is an economic harm – possible reduced revenues – that is routinely addressed through monetary damages. And if this were not enough to make Ortho/J&J’s tactics untenable, it asks this Court to consider entering this unprecedented relief – relief that would result in the loss of discounts to customers and grievously ill patients – on a truncated factual record to be developed over a mere 26 days.

Under these circumstances, Ortho/J&J’s requests for expedited discovery and a rush to a preliminary injunction should be denied. This matter should proceed on a schedule that will permit both parties full opportunity to conduct the necessary discovery, prepare expert testimony,

¹ Amgen USA Inc., erroneously named and sued as Amgen Inc., hereby voluntarily submits to the jurisdiction of this Court.

and present the critical evidence that this Court will need to render a decision that will affect hundreds of thousands of patients.

There are several independent reasons why Ortho/J&J's motion should be denied. First, there is no immediacy to this issue. The pricing and marketing issues raised by Ortho/J&J are simply modifications to a well-established Amgen discount program that even by Plaintiff's own allegation has been "coercive" for over 18 months. In fact, Amgen's discounts are themselves a response to Ortho/J&J's own pricing and marketing strategies in this same market. The expedited discovery schedule requested by Ortho/J&J is designed to focus the Court on only a part of the relevant record. Ortho/J&J wants to focus on pricing decisions made by Amgen as if they occurred in a vacuum, without allowing any opportunity for Amgen to develop the competitive and market-driven decisions made by Ortho/J&J. Full discovery will show that Ortho/J&J is itself a fierce and effective competitor, which has and uses many competitive tools to compete against Amgen for the sale of RBCGF.

Second, the alleged harm – lost sales – would be fully compensable in money damages. In fact, Ortho/J&J quantified its alleged harm in the papers submitted to this Court. Unlike the cases cited by plaintiff, Ortho/J&J an operating company of a Fortune 50 company, will hardly disappear if an injunction is not entered. We are not aware of any case where a court entered a preliminary injunction on the implementation of a discount program.

Third, entry of a preliminary injunction would be contrary to the public interest because it would prevent Amgen from continuing to provide discounts to the Government and consumers. Simply put, Ortho/J&J asks this Court to eliminate competition.

Fourth, the issues presented by plaintiff's claims are complex and traditionally resolved through full discovery. The antitrust issues presented here include: whether the "relevant

market” is limited to a single channel of sales (oncology clinics) or, in fact, includes other non-dialysis RBCGF sales; whether Amgen’s contracts constitute “tying” or are, in fact, procompetitive discounting; whether Amgen’s discounts are intended to “monopolize” a market or are a defensive response to Ortho/J&J’s own competitive advantages; and whether Ortho/J&J has a myriad of options (such as by lowering the price of Procrit® or continuing to bundle its own products as it has in the past) by which to compete with Amgen’s lawful conduct. All of these legally, economically, and factually complex issues will need to be fully explored before this case will be ripe for adjudication.

Many aspects of Plaintiff’s claims are in serious doubt, including whether it will ultimately be able to prove *any* of the many elements of its antitrust claims. Two things are, however, certain: entering the requested preliminary injunction would raise prices, and the complex issues in this case cannot be resolved via a truncated record.

Against this backdrop, the supposed urgency of Ortho/J&J’s motion falls away, and the true purpose of Ortho/J&J’s Complaint becomes clear. Plaintiff’s Complaint in this case is just the latest of many efforts by Ortho/J&J to limit Amgen’s ability to compete. The parties’ rights in this complex antitrust action cannot be decided on a partial record, and considerably more than the 26 days suggested by Ortho/J&J will be necessary. In the meantime, Ortho/J&J will certainly continue to be able to compete against Amgen. And, in the unlikely event it should ultimately prevail, Ortho/J&J can be made whole by an award of money damages. For all these reasons, Ortho/J&J’s motion should be denied.

STATEMENT OF FACTS

Many of the alleged “facts” set out in Ortho/J&J’s pleadings are in dispute and will need to be resolved by the Court before ruling on Ortho/J&J’s motion for preliminary relief. We

summarize below key facts as they relate to the Motion for Expedited Discovery that Amgen hopes will be helpful to the Court.

1. Aranesp® Was An Innovative Breakthrough, Beneficial To Patients In Need Of RBCGF, That Has Resulted In Increased Competition

Anemia is commonly seen in patients with chronic kidney disease, cancer, and HIV, among other conditions. Anemia is caused by the depletion of the human hormone erythropoietin, and Amgen research scientists were the first to produce this hormone in a form and quantity which made therapeutic use possible. These discoveries led to the development of Epoetin alfa, a synthetic form of erythropoietin, which stimulates the production of red blood cells.

Amgen licensed Ortho/J&J in 1985 to market and sell Epoetin alfa in the United States for certain applications excluding dialysis (“Product License Agreement” or “PLA”). Ortho/J&J introduced its branded Epoetin alfa – Procrit® – in 1991, and enjoyed a monopoly position in non-dialysis RBCGF patients for more than a decade as it faced no competition until 2002. In 1997, Ortho/J&J sued Amgen over the rights to a new product, darbepoetin alfa, which Amgen markets under the name Aranesp®. Ortho/J&J claimed it had rights to the new product by virtue of the PLA. After approximately two years of litigation, an arbitration panel entered a unanimous opinion denying Ortho/J&J any rights to Aranesp®.

The introduction of Aranesp® was the result of extensive research and development by Amgen, and represented a critical innovation in the area of anemia treatment. Due to its longer serum half-life – *i.e.*, it circulates longer in the body than Procrit®. It was not, as Ortho/J&J contends, undertaken as a design to interfere with Ortho/J&J’s monopoly by “circumventing” its contractual obligations. The introduction of Aranesp®, however, did cause Ortho/J&J to face competition in the non-dialysis RBCGF market for the first time, and resulted in Ortho/J&J

lowering the price of Procrit®. As a practical matter, the introduction of Aranesp® has thus had the effect of increasing competition in RBCGF.

This lawsuit by Ortho/J&J is the latest battle in a long war between these two companies over Procrit®. Since Amgen invented Epoetin alfa, which Ortho/J&J currently sells as Procrit®, in 1983 and granted a limited license to Ortho/J&J in 1985, Ortho/J&J has asserted claims in five disputes between Amgen and Ortho/J&J over the manufacture, license, and distribution of Procrit® and Aranesp® against Amgen.

- In 1989, Ortho/J&J filed an arbitration claim alleging that Amgen had breached its obligations to supply Ortho/J&J with its U.S. Epoetin alfa requirements and failed to assist Ortho/J&J in achieving its FDA licensure. Pursuant to the arbitrator's order, the parties negotiated a subsequent distribution agreement.
- In 1991, Ortho/J&J filed an arbitration claim to obtain its own FDA license to manufacture Procrit® because its distributorship arrangement with Amgen was commercially disadvantageous. Ortho/J&J's request was denied.
- In 1997, Ortho/J&J claimed in arbitration that it had rights to market and sell Aranesp® pursuant to the PLA. The arbitration panel unanimously concluded that Ortho/J&J had no rights to Aranesp® whatsoever.
- In 2000, Ortho/J&J filed a counter-demand in an ongoing arbitration asking the arbitrator to find that Amgen had intentionally promoted and sold Epoetin alfa for non-dialysis use and that Amgen had not fulfilled its obligations to assist Ortho/J&J with development work with regard to Procrit®. Ortho/J&J's demands, along with its \$500 million damages claim, were dismissed by the arbitrator.
- In 2005, Ortho/J&J asked an arbitrator to allow it to hold its own FDA license for Epoetin alfa produced by Amgen. This arbitration is currently pending.

2. Customers Are Neither Contractually Nor Economically Compelled To Buy Aranesp®

Amgen neither contractually obligates, nor economically compels, customers to purchase Aranesp®. Healthcare professionals make decisions on the use of medicines based on a patient's unique clinical circumstances and the efficacy and safety of medicines; economics are secondary to any such decision. Amgen has made available additional discounts to customers who also use

white blood cell growth factor (“WBCGF”) to help protect patients receiving chemotherapy from infection.² Amgen offers such discounts to oncology customers who purchase Aranesp® and its WBCGF products Neupogen® and Neulasta®. Amgen has always offered and continues to offer the option of purchasing these products separately, and also offers discounts on such single-product purchases.

Despite the existence of Amgen’s discounts for customers purchasing Aranesp® and Neupogen® and/or Neulasta®, many clinics have chosen not to meet the Aranesp® purchase thresholds to qualify for these discounts. Many Neupogen® and Neulasta® customers have continued to purchase Procrit® for the vast majority of their RBCGF requirements. Thus, when deciding whether to accept a discount for Aranesp® and Neupogen® and/or Neulasta®, customers have a choice – and they exercise that choice.

Furthermore, Ortho/J&J mischaracterizes the economics of oncology clinic reimbursements. Ortho/J&J emphasizes Medicare reimbursement levels in its allegations, but as Ortho/J&J concedes, Medicare patients constitute less than half of patients seen by oncology clinics. Ortho/J&J fails to mention that reimbursements received from private payers are typically *higher* than Medicare. Ortho/J&J paints a dire, if completely inaccurate, picture of the choices faced by an oncology clinic, when in fact oncology clinic economics are based on the clinic’s patient mix between private payer patients and Medicare patients. In general, oncology clinics are profitable because of this patient mix. Moreover, the primary driver of any decision by a doctor to use a particular medicine is what is in the best interest of the patient, not economics.

² Amgen sells WBCGF under the brand names Neupogen® and Neulasta®. Neulasta® has a unique structure that allows it to remain in the body much longer and be administered only once per chemotherapy cycle – a meaningful benefit for patients and their caregivers.

3. Revisions To Amgen's Discount Program, Effective October 1, 2005, Modify Amgen's Nearly Two-Year-Old Discount Program

The Amgen discount program that took effect October 1, 2005 does not change the fundamental structure of the discount program that Amgen introduced nearly two years ago.

Notably, while Amgen's discount program structure has been consistent, government regulation of the reimbursement of drugs has changed dramatically since January 1, 2005, due to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Modernization Act"). Moreover, further change is anticipated that will provide clinics and physicians with even greater reimbursement options. Thus, as Ortho/J&J apparently concedes, the extent to which the environment for RBCGF sales have changed is due in large part to the changing environment of government regulation, over which Amgen has no control.

4. Oncology Clinics Are Only One Type Of RBCGF Customer

There are many RBCGF customers, including oncology clinics, hospitals, nephrology clinics, retail pharmacies, long term care facilities, and other health care providers. Oncology clinics are simply one channel to reach RBCGF patients and are not a unique market for several reasons, including:

- The form of Procrit® and Aranesp® sold does not vary by customer. For example, the Procrit® sold to a clinic is identical to the Procrit® sold to a hospital, long-term care facility, retail pharmacy, or any other provider.
- Pursuant to the Medicare Modernization Act the reimbursement rate for RBCGF in the clinic setting is determined by calculating the average net sales price ("ASP") (list price less discounts) across *all* RBCGF sales to *all* commercial U.S. customers. For example, the ASP for Procrit® is determined by Ortho/J&J's Procrit® sales to all commercial customers, including oncology clinics, hospitals, retail sales, nephrology clinics, long term care facilities, as well as any other sales.
- Patients can obtain the same RBCGF treatment from different types of care providers. For example, a patient receiving Procrit® treatment in a clinical setting could receive the same treatment in a hospital, or any of a variety of other health care facilities.

5. Ortho/J&J, Which Had An Eleven Year Monopoly In RBCGF, Currently Has Approximately 50% Market Share Of The RBCGF Market

Ortho/J&J enjoyed a monopoly in RBCGF for eleven years for all non-dialysis indications. Fourteen years after Procrit® was introduced, Ortho/J&J still maintains approximately 50% of all RBCGF non-dialysis sales. As a further indication of Ortho/J&J's strong position, by its own admission Ortho/J&J accounts for 70% of RBCGF sales to retail pharmacies.

6. Ortho/J&J Has Numerous Options For Competing With Amgen

Ortho/J&J is a very large, sophisticated, and profitable company that, as part of what it self-describes as “the world’s most comprehensive and broadly based manufacturer of healthcare products,” is well-equipped to compete vigorously for RBCGF sales, and is not foreclosed from making RBCGF sales to any customer – now or in the future. Ortho/J&J has extensive resources at its disposal and has numerous options for competing for RBCGF sales to all customers. For example:

- Lower prices. Ortho/J&J has low costs of goods associated with Procrit®, and substantial gross profit margins. For oncology patients treated in hospitals, clinics and retail settings, the most frequently administered dose of Procrit® is more expensive than the most frequently administered dose of Aranesp®.
- Bundling. Ortho/J&J regularly offers bundled discounts across its broad basket of products. For example, in the oncology clinic setting, Ortho/J&J bundles Procrit® with Doxil®, a unique chemotherapy treatment. In the hospital setting, Ortho/J&J bundles Procrit® discounts with discounts on essential hospital products, including everything from advanced medical devices (*e.g.*, stents) to adhesive strips. In the long-term care setting, Procrit® is regularly bundled with Risperdal®, a leading antipsychotic drug.
- Loyalty Discounts. Ortho/J&J often bases discounts – including Procrit® discounts – on various “loyalty” factors, such as high minimum purchase thresholds and the length of time a customer has purchased from Ortho/J&J.
- Large Sales Force. Ortho/J&J has among the largest forces dedicated to sales and marketing of pharmaceutical products.

Furthermore, many patients are treated for conditions that require only RBCGF and not WBCGF therapy. In these situations, the Amgen discount program proves less useful for customers.

7. Ortho/J&J Can Profitably Discount Prices To Oncology Clinics

Ortho/J&J's strength in RBCGF sales gives it the capacity to profitably discount prices to oncology clinics. For example, as Ortho/J&J affirmatively states, Ortho/J&J accounts for 70% of RBCGF sales to retail customers, to whom discounts are not typically offered. With its profitable customer base, Ortho/J&J could thus offer substantial Procrit® discounts to oncology clinics. Ortho/J&J's ability to profitably offer such discounts is underscored by its robust gross profit margin on overall Procrit® sales.

8. Amgen's Discount Program Is A Defensive Move In Response To The Many Competitive Advantages Of Procrit®

Amgen's discounts offered to oncology clinics are only one of many discount practices utilized by both companies to compete for RBCGF sales. Amgen's discount programs have traditionally been defensive, given the numerous competitive advantages of Ortho/J&J, a large, sophisticated and diversified company. As described above, some of those advantages include the ability to bundle across a wide variety of products, high profit margins, low cost of goods for Procrit®, a large dedicated sales force, and an entrenched position in the RBCGF market.

Faced with such a robust competitor for RBCGF sales, Amgen defensively offered discounts to customers purchasing some combination of Aranesp® and Neupogen® and/or Neulasta®. This defensive discounting strategy neither contractually nor economically compels customers to purchase Aranesp® at the expense of Procrit®. Indeed, a significant number of Amgen's customers reject the additional discount altogether and instead historically have

purchased and continue to purchase Procrit® from Ortho/J&J and Neupogen® and/or Neulasta® from Amgen.

ARGUMENT

I. ORTHO/J&J'S MOTION FOR EXPEDITED DISCOVERY SHOULD BE DENIED

Ortho/J&J's Motion for Expedited Discovery should be denied for several reasons. First, Ortho/J&J faces no imminent harm that would not be compensable by money damages should Ortho/J&J prevail. The risk of proceeding on a truncated record is high, and the consequences are severe since the harm of losing discounts will fall on customers and ultimately on patients. Second, entry of the relief sought by Ortho/J&J will harm competition and change the status quo because, if granted, it would force Amgen to halt its discount programs which have been in place for nearly two years and prevent it from offering customers *any* combined discounts on Aranesp® and Neupogen® and Neulasta®. Third, the accelerated, truncated review Ortho/J&J advocates is inconsistent with the teaching of the Supreme Court and Third Circuit, which, as discussed below, have both admonished courts to be cautious when reviewing pricing arrangements, which can often be procompetitive.

A. Ortho/J&J's Alleged Harm Is Not Irreparable, And Is Fully Compensable By Money Damages

The Third Circuit has stated: "We have recognized many times that the grant of injunctive relief is an extraordinary remedy which should be granted only in limited circumstances." *Frank's GMC Truck Center, Inc. v. Gen. Motors Corp.*, 847 F.2d 100, 102 (3d Cir. 1988) (citation omitted). If a plaintiff fails to establish that the defendant's conduct will cause irreparable harm, its request for preliminary injunctive relief must be denied. *See, e.g., Ortho Diagnostic Sys., Inc. v. Abbott Labs., Inc.*, 822 F. Supp. 145, 147 (S.D.N.Y. 1993) (Docket

No. 93-cv-2656) (“Because we find that [Ortho] has not demonstrated a likelihood that it will suffer irreparable harm . . . we must deny the preliminary injunction.”). In the instant case, Ortho/J&J complains that Amgen’s discount programs will cause Ortho/J&J to lose sales and “goodwill.” Neither loss of sales nor loss of goodwill, however, justifies injunctive relief. Ortho/J&J’s extensive papers filed with this Court acknowledge that its alleged harm is not imminent, but may only occur in the future (See Plaintiff’s Memorandum at 15). Since Ortho/J&J cannot establish a critical requirement of the preliminary injunction standard, its request for expedited discovery is completely unwarranted and should be denied.

1. Ortho/J&J’s Alleged Harm Is Compensable And Calculable

To establish irreparable harm, the Supreme Court has made clear that “[m]ere injuries, however substantial, in terms of money, time and energy . . . are not enough. The possibility that adequate compensatory or other corrective relief will be available at later date . . . weighs heavily against a claim of irreparable harm.” *Sampson v. Murray*, 415 U.S. 61, 90 (1974) (quotation omitted). “The Court of Appeals for the Third Circuit has consistently held that financial or economic injury does not constitute irreparable harm necessary to support an award of injunctive relief.” *Cent. Jersey Freightliner, Inc. v. Freightliner Corp.*, 987 F. Supp. 289, 296 (D.N.J. 1997) *citing* *Acierno v. New Castle County*, 40 F.3d 645, 653 (3d Cir. 1994) and *Hohe v. Casey*, 868 F.2d 69, 73 (3d Cir. 1989).

Ortho/J&J speaks of its “inability to compete” for non-dialysis RBCGF sales, and loss of “relationships,” but the essence of Ortho/J&J’s complaint is that it will lose *sales* of Procrit® as a result of price competition with Aranesp®. Quite simply, lost sales do not constitute irreparable harm. *See, e.g., J&M Turner, Inc. v. Applied Bolting Tech. Prods. Inc.*, Nos. 95-2179, 96-5819, 1997 U.S. Dist. LEXIS 1835, at *56 (E.D. Pa. Feb. 20, 1997) (“[L]ost sales

would not constitute irreparable harm.”). When a party’s purported harm “centers on the loss of money” the irreparable harm test is not satisfied because “money damages will fully compensate” a harmed party. *Instant Air Freight Co. v. C.F. Air Freight Inc.*, 882 F.2d 797, 801 (3d Cir. 1989). Ortho/J&J’s harm is *not* “of a peculiar nature [such that] compensation in money cannot atone for it.” *Glasco v. Hills*, 558 F.2d 179, 181 (3d Cir. 1977).

Ortho/J&J’s claimed future harms are strikingly similar to those Ortho Diagnostic Systems (“Ortho”), another J&J operating company, claimed in its motion for preliminary injunction challenging Abbott Laboratories’ bundled discounting arrangement. There, Abbott argued that “even if Ortho/J&J proves its antitrust claims, its only damages will be loss of customers, an injury which can be fully compensated by monetary relief.” *Abbott Labs.*, 822 F. Supp. at 151. The Southern District of New York agreed: “Ortho’s losses, if any, can be compensated by money damages. Ortho will be able to demonstrate which customers switched from Ortho to Abbott, and the amount of revenues foregone from that loss of business.” *Id.* Ultimately, Ortho never had the opportunity to prove damages because Abbott’s bundled discount program was found to be lawful and procompetitive. *Ortho Diagnostic Sys. v. Abbott Labs.*, 920 F. Supp. 455 (S.D.N.Y. 1996). Likewise, the District of New Jersey has held that loss of good will may be compensable with money damages, and therefore “does not constitute irreparable harm.” *Cent. Jersey Freightliner*, 987 F. Supp. at 296.

Moreover, when historical sales data are available, calculation of lost sales is a relatively simple exercise, and a party cannot reasonably claim that a money damages award is inadequate. *See Instant Air Freight*, 882 F.2d at 802 (money damages ascertainable; 20 years sales history “admit[s] of a ready mathematical computation”). Again, the essence of Ortho/J&J’s alleged “harm” is loss of Procrit® sales, a product that Ortho/J&J has marketed for years. Given

Procrit's® sales history dating to 1991, it strains credulity for Ortho/J&J to claim that money damages for lost sales of Procrit® are incalculable. "[W]ithout a demonstration of why losses cannot be calculated, irreparable harm does not exist." *Bascom Food Prods. Corp. v. Reese Finer Foods, Inc.*, 715 F. Supp. 616, 640 (D.N.J. 1989). Ortho/J&J has not, and cannot, make such a demonstration, and thus fails to establish a *necessary* element of the preliminary injunction standard. In sum, Ortho/J&J has failed to establish that it faces impending, irreparable harm that would even remotely justify a rush to judgment on a hastily assembled and incomplete record.

2. Ortho/J&J Cites No Case In Which Irreparable Harm Was Found Under Even Remotely Analogous Facts or Legal Claims

Ortho/J&J does not cite a single case with analogous facts or legal claims, where the district or appellate court made a finding of irreparable harm. Unlike Ortho/J&J, successful plaintiffs in Ortho/J&J's cited cases alleged irreparable harm that was neither compensable nor calculable. For example, much of Ortho/J&J's legal authority is drawn from cases where the plaintiff's very existence in the market was threatened, a situation that Ortho/J&J does not allege. *See, e.g., Bascom Food Prods. Corp.*, 715 F. Supp. at 640 (cited in Plaintiff's Mem. of Law, at 34); *Id.* at 640 (cited in Plaintiff's Mem. of Law, at 34); *Yong Ki Hong v. KBS Am., Inc.*, No. 05-CV-1177, 2005 WL 1712236, at *2 (E.D.N.Y. Jul. 22, 2005) (cited in Plaintiff's Mem. of Law, at 35); *Tully v. Mott Supermarkets, Inc.*, 337 F. Supp. 834, 851 (D.N.J. 1972) (cited in Plaintiff's Mem. of Law, at 35); and *Bristol Tech., Inc. v. Microsoft Corp.*, 42 F. Supp. 2d 153, 161 (D.Conn. 1998) (cited in Plaintiff's Mem. of Law, at 37). Ortho/J&J also relies on cases where irreparable harm was premised on harms wholly unrelated to the harm Ortho/J&J alleges. *See, e.g., Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 596 (3d Cir. 2002) (false advertising, cited in Plaintiff's Mem. of Law, at 35); *Pappan*

Enters., Inc. v. Hardee's Food Sys., 143 F.3d 800, 805 (3d Cir. 1998) (loss of reputation to trademark, cited in Plaintiff's Mem. of Law, at 35); and *C&A Carbone, Inc. v. Clarkstown*, 770 F. Supp. 848, 854 (S.D.N.Y. 1991) (deprivation of constitutional rights, cited in Plaintiff's Mem. of Law, at 35).

Ortho/J&J's papers fail to allege requisite facts or cite case law to support its claim of irreparable harm. Ortho/J&J's request for expedited discovery, an onerous burden on the parties and this Court, is thus unwarranted and should be denied, given the lack of imminent, irreparable harm, without which the Court cannot issue the preliminary injunction – an “extraordinary remedy” – Ortho/J&J seeks.

B. Ortho/J&J Has Substantial Marketing Resources, And Amgen's Discount Program Does Not Result In Any Significant Foreclosure

Ortho/J&J's claim that it is unable to compete in sales for RBCGF, and that it will suffer irreparable harm, is disingenuous based on the facts alleged and on common sense. Ortho/J&J is an operating company of one of the world's largest and most profitable companies, and is well-equipped to compete vigorously for non-dialysis RBCGF sales. In view of Ortho/J&J's approximately 50% share of non-dialysis RBCGF sales, Amgen's discount program does not foreclose Ortho/J&J's ability to market and sell RBCGF. Moreover, Ortho/J&J has extensive resources at its disposal and has numerous options for competing for non-dialysis RBCGF sales, including for example:

- *Ortho has low cost of goods and high profit margins for Procrit®.* Ortho/J&J has low cost of goods associated with Procrit®, and high gross profit margins. These high margins allow Ortho/J&J to compete vigorously for non-dialysis RBCGF sales and, in particular, to compete with any discount offered by Amgen on Aranesp®.
- *Ortho/J&J has a broad portfolio of products from which it can and does bundle.* Ortho/J&J regularly offers bundled discounts across its broad basket of products. In the oncology setting, Ortho/J&J bundles Procrit® with Doxil®, a unique

chemotherapy treatment. In the hospital setting, Ortho/J&J (and J&J) bundles Procrit® discounts with discounts on essential hospital products, including everything from advanced medical devices (*e.g.*, stents) to adhesive strips. Its portfolio of products allows it to compete with Amgen step-for-step. This range of products has historically provided Ortho/J&J with a competitive advantage through the offering of bundled discounts. In fact, Ortho/J&J has offered customers increased discounts based on the length of time the customer has purchased from Ortho/J&J.

- *Ortho/J&J's eleven year monopoly in non-dialysis RBCGF indications accords it unique competitive advantages.* Ortho/J&J draws on significant resources it has gained through years as a monopolist in the RBCGF market and through its position as a subsidiary of J&J. Ortho/J&J has among the largest forces dedicated to sales in the pharmaceutical industry. Many patients are treated for conditions that require only RBCGF. Thus, Ortho/J&J has several avenues for Procrit® sales and is not foreclosed from competing for non-dialysis RBCGF sales.
- *Ortho/J&J is well-equipped to compete.* Ortho is an operating company of J&J, a Fortune 50 company which boasts a broad product portfolio, over \$47 billion in sales and \$8.5 billion in profit in 2004. As the Southern District of New York suggested in 1993, a company positioned similarly to Ortho/J&J can sustain virtually any reduced revenues that might occur as a result of increased competition from a competitor. *See Ortho Diagnostic Sys., Inc.*, 822 F. Supp. at 151 (finding that Ortho suffered no irreparable harm since it faced only lost sales and potential lost opportunities, both of which were compensable by money damages, and further finding that, as a subsidiary of J&J (which then had sales of \$13.9 billion), Ortho could sustain loss of revenues resulting from increased competition).

Given its vast resources, Ortho/J&J is able to engage in vigorous competition if it chooses to do so.

C. Entry Of A Preliminary Injunction would Alter The Status Quo, And Would Likely Harm Customers And Patients

Ortho/J&J's request for preliminary injunctive relief in this case in effect asks this Court to relieve it from the obligation of competing by claiming that Amgen's discount program has foreclosed it from competing. Entry of the relief sought by Ortho/J&J would harm competition and change the status quo by halting Amgen's discount program. The extraordinarily broad Order that Ortho/J&J seeks would effectively enjoin Amgen from combining discounts on its

Aranesp® and Neupogen® and Neulasta® products – a well-established practice. *See, e.g.*, discussion more fully laid out in 19-23, *infra*. Customers and patients would bear the brunt of this injunction, as they would face lower discounts for these products. Because of these very types of risks, the Supreme Court has stated that courts must be careful in scrutinizing pricing arrangements, which can be procompetitive. *See Brooke Group, Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1993). The Third Circuit has likewise admonished courts to carefully review pricing claims. Because the relief sought by Ortho/J&J would prevent further implementation of the discount arrangement, its motion should be denied.

Ortho/J&J is fully able to compete with Amgen, and this Court should not relieve Ortho/J&J of that responsibility by enjoining Amgen's discount program – effectively raising prices and disadvantaging customers. Such relief would only be appropriate after full discovery, at which time this Court may adjudicate these issues on a full record. The risk of a false positive in this case is simply too great to entertain Ortho/J&J's request for preliminary relief, or to order expedited discovery. Ortho/J&J will suffer no harm that cannot be compensated by money damages, but if Amgen is forced to halt its discount program, customers and grievously ill patients will necessarily face lower discounts for Aranesp®, Neulasta® and/or Neupogen®.

D. Ortho's Claims Present Complex Factual and Legal Issues Which are Likely to be Resolved against Ortho/J&J

1. Ortho/J&J Has Failed To Allege a Proper Relevant Antitrust Market

Ortho/J&J has failed to allege a proper relevant antitrust market to support its antitrust claims, which will be fatal to those claims. *See, e.g., Barr Labs., Inc. v. Abbott Labs.*, No. 87-4764, 1991 U.S. Dist. LEXIS 17690 (D.N.J. Nov. 29, 1991) (granting summary judgment against Section 1 and Section 2 claims where plaintiff failed to show market power in relevant market); *Columbia Metal Culvert Co. v. Kaiser Aluminum & Chem. Corp.*, 579 F.2d 20 (3d Cir.)

(affirming directed verdict against Section 1 claim for failure to define proper relevant market) *cert. denied*, 439 U.S. 876 (1978); *Pa. Dental Ass'n v. Med. Serv. Ass'n*, 745 F.2d 248, 261 (3d Cir. 1984) (affirming summary judgment against monopolization claims when relevant market was not supported by evidence), *cert. denied*, 471 U.S. 1016 (1985); *Syncsort Inc. v. Sequential Software, Inc.*, 50 F. Supp. 2d 318, 331 (D.N.J. 1999) (dismissing monopolization counterclaim for failing to plead facts to support alleged relevant market of sorting software for a particular operating system).

A relevant product market consists of “products that have reasonable interchangeability for the purposes for which they are produced – price, use, and qualities considered.” *United States v. E. I. Du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956); *see also SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1063 (3d Cir.), *cert. denied*, 439 U.S. 838 (1978) (adopting the *Du Pont* approach and characterizing the process of defining a relevant market as “describing those groups of producers which, because of the similarity of their products, have the ability – actual or potential – to take significant amounts of business away from each other”). The Third Circuit has cautioned that the legal “guidelines offer no precise formula for judgment [in determining relevant markets] and they necessitate, rather than avoid, careful consideration *based on the entire record.*” *Columbia Metal Culvert Co.*, 579 F.2d at 28 (emphasis added).

Case law establishes that Ortho/J&J’s alleged market – limited to oncology clinics – is erroneous. This Court has previously declined to define a relevant market limited to pharmaceutical sales to customers in a particular channel of distribution in a similar antitrust suit. *Barr Labs., Inc.*, 1991 U.S. Dist. LEXIS 17690, at *7-8 (finding sales of erythromycin to warehousing chain drug stores did not constitute a relevant market when the same product was sold in other channels); *see also PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101 (2d Cir. 2002)

(rejecting market definition limited to soft drinks sold in one channel of distribution when those same drinks were sold in other channels); *Lockheed Martin Corp. v. Boeing Co.*, 314 F. Supp. 2d 1198 (M.D. Fla. 2004) (rejecting market definition limited to satellite launch services sold to the U.S. Government when the same vehicles are also sold to other types of customers).

Here, oncology clinics do not constitute unique customers of RBCGFs (as alleged by Ortho/J&J) because the *same* RBCGFs sold to the oncology clinics are also sold to hospitals, retail pharmacies, nephrology clinics, long-term care facilities, and other customers. Patients can receive the product from many types of RBCGF customers. Moreover, the Federal government computes the Medicare reimbursement about which Ortho/J&J complains (Plaintiff's Memorandum at 15-17) on the basis of the average selling prices for RBCGFs sold to oncology clinics *and virtually all other customers*, excluding certain Government agencies and programs. Thus, sales of RBCGFs to oncology clinics only do not exhibit the "practical indicia" of properly defined relevant markets. *Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962).

For these reasons, the relevant market proposed by Ortho/J&J is erroneous. Therefore, Ortho/J&J is unlikely to prevail on the merits of its antitrust claims.

2. The Discounting About Which Ortho/J&J Complains Does Not Constitute Tying In Violation Of Section 1 Of The Sherman Act

Contrary to Ortho/J&J's arguments, Amgen's discount program does not constitute unlawful tying in violation of Section 1 of the Sherman Act. In particular, Ortho/J&J has failed to show that Amgen's discount program conditions the purchase of Neupogen® or Neulasta® on the purchase of Aranesp®.

For a violation of Section 1 to occur under a tying theory, defendant must condition the sale of its tying product on the buyer's purchase of the tied product or coerce the buyer into buying a product he does not want. *N. Pac. Ry. v. United States*, 356 U.S. 1, 5-6 (1958).

Ortho/J&J, however, has not alleged any such conditioning. Instead, Ortho/J&J's own Memorandum states that Amgen offers *discounts, not products*, on the condition that certain volumes of purchases are met. Memorandum at 8 ("Amgen began offering substantial "rebates" to oncology clinics on the condition that these facilities reach combined volume requirements for Amgen's RBCGF and WBCGF drugs. . . ."); *Id.* at 10 (alleging Amgen gained 65% share "by tying access to WBCGF drug *rebates*" to purchases of its RBCGF) (emphasis added).

In the context of packaged discounts, leading antitrust scholars state, "To determine whether a package discount mimics a refusal to sell [the] tying product . . . separately, most courts consider the proportion of separate purchases. The greater that proportion, the less a package discount resembles the classic tie." 10 Areeda & Hovenkamp, *Antitrust Law*, ¶ 1758b, 327 (2d ed. 2005), *citing, inter alia, Ways & Means, Inc. v. IVAC Corp.*, 506 F. Supp. 697, 701-02 (N.D. Cal. 1979), *aff'd*, 638 F.2d 143 (9th Cir. 1979) (no de facto tie because 25 percent of the tying product sales were separate).

Ortho/J&J relies principally upon *Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 452 (3d Cir. 1977) for the proposition that a plaintiff need not show coercion when a contract has the "practical economic effect of precluding sale of other than the [seller's product.]" Memorandum at 22-23. Ortho/J&J's arguments, however, misstate the law in this Circuit. *Bogosian* simply held that proof of coercion is not required when the plaintiff can show express conditioning. 561 F.2d at 452. Moreover, courts within this circuit now doubt the validity of *Bogosian*. See *Kellam Energy, Inc. v. Duncan*, 668 F. Supp. 861, 882 (D. Del. 1987) ("Even *Bogosian*'s narrow holding is no longer valid after the Supreme Court reconsideration of per se tying arrangements in *Jefferson Parish Hospital Dist. No. 2 v. Hyde*, 466 U.S. 2 (1984)). The Court there suggested that *direct proof* of coercion is essential to maintain an action for an illegal tie-in.") (emphasis

added). Indeed, the *Bogosian* District Court adopted this view on remand, as *Bogosian* was decided before *Jefferson Parish. Bogosian v. Gulf Oil Corp.*, 596 F. Supp. 62, 76 (E.D. Pa. 1984).

Here Amgen's discount program is not analogous to the cases upon which Ortho/J&J relies. Those cases involved actual conditioning of sales of tying product upon sales of a tied product. By Ortho/J&J's own admission, Amgen does no such thing. Memorandum at 8-10. Customers can and do purchase WBCGF and RBCGF independently of each other. Thus, Ortho/J&J has failed to demonstrate direct proof of coercion as required to sustain a tying claim as required by *Jefferson Parish. Accord Kellam Energy*, 668 F. Supp. at 882 ("The Court there suggested that *direct proof* of coercion is essential to maintain an action for an illegal tie-in.") (emphasis added).

Moreover, "tying may have procompetitive justifications that make it inappropriate to condemn without *considerable* market analysis." *NCAA v. Board of Regents*, 468 U.S. 85, 104 (1984) (emphasis added). Indeed, "[o]ver time, many commentators and the Antitrust Division of the Justice Department have suggested that even tie-ins in concentrated markets may serve procompetitive purposes, such as quality control, production and sales efficiencies, and facilitation of indirect price competition." *Town Sound & Custom Tops, Inc. v. Chrysler Motors Corp.*, 959 F.2d 468, 477 (3d Cir. 1992). All of these considerations make it inappropriate for the Court to grant Ortho/J&J's motion for preliminary injunction of Amgen's discounting program on the basis of expedited discovery.

3. Amgen's Discounting Program is not Attempted Monopolization

Amgen's discounting program does not constitute predatory or anticompetitive conduct that can support a claim of attempted monopolization in violation of Section 2 of the Sherman

Act. Fundamentally, Amgen's program offers customers greater discounts, an outcome the antitrust laws encourage, not prohibit.

To succeed on its attempted monopolization claim, Ortho/J&J must show that Amgen has engaged in predatory or anticompetitive conduct. *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993). However, the antitrust laws promote, not prohibit, vigorous competition such that Amgen's discounting is entirely legal. As this Circuit has said, "Actions that promote efficiency and lower prices in the marketplace, for example, may cause economic loss to competitors. Conduct that harms competitors may benefit consumers – a result the antitrust laws were not intended to penalize." *Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 109 (3d Cir. 1992). It is precisely for that reason that "[c]ourts have carefully scrutinized enforcement efforts by competitors because their interests are not necessarily congruent with the consumer's stake in competition." *Alberta Gas Chems., Ltd. v. E. I. duPont de Nemours & Co.*, 826 F.2d 1235, 1239 (3d Cir. 1987), *cert. denied*, 486 U.S. 1059 (1988).

Ortho/J&J has failed to show that Amgen has the specific intent to monopolize the alleged market of sale of RBCGF drugs to oncology clinics. Instead, it relies upon conclusory allegations in an attempt to attack a legitimate discounting program that results in lower prices for consumers. To prevail on a claim of attempted monopolization, Ortho/J&J must show that Amgen had "a specific intent to destroy competition or build monopolies." *Times-Picayune Publ'g Co. v. United States*, 345 U.S. 594, 626 (1953). A mere desire to increase market share or win customers from a competitor does not satisfy this standard. *See Spectrum Sports*, 506 U.S. at 459; *Structure Probe, Inc. v. Franklin Inst.*, 450 F. Supp. 1272, 1287 n.16 (E.D. Pa. 1978) (efforts to pursue normal business goals of increased sales and additional market share not forbidden by Sherman Act).

Here, Amgen's actions were defensive in nature. Amgen designed its discount program to respond to Ortho/J&J's dominance in non-dialysis RBCGF sales, which includes sales to hospitals and retail drug stores, among others. Ortho/J&J actually has approximately 50% of all non-dialysis RBCGF sales. Additionally, Ortho/J&J's share of sales to customers other than oncology clinics and nephrology clinics exceeds Amgen's share. For example, Ortho/J&J's own papers reveal that it has 70% of non-dialysis RBCGF sales to retail drug stores alone. Memorandum at 10. The purpose of the antitrust laws is to protect competition, not competitors. *Cargill, Inc. v. Monfort*, 479 U.S. 104, 110 (1986) (citing *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977)). For these reasons, the Court cannot conclude, especially without full discovery, that Amgen's discount program gives rise to an inference of a "specific intent to destroy competition or build monopol[ies]." *Times-Picayune*, 345 U.S. at 626.

Ortho/J&J's Complaint thus includes serious facial problems on the merits of its claim, while raising complex factual and legal issues. The risk of an error is serious in this case, given that customers and patients will be required to forego discounts if Amgen is enjoined from offering discounts to compete with Ortho/J&J. For these reasons, the Court should only adjudicate this matter on a full record, which simply cannot be developed in thirty days or less, and should deny Ortho/J&J's Motion for Expedited Discovery.

II. ORTHO/J&J'S CLAIMS SHOULD BE RESOLVED ON A FULLY DEVELOPED RECORD

The legal and factual issues raised by Ortho/J&J's claims should not be resolved on anything less than a fully developed record. To our knowledge, no court has ever issued a preliminary injunction in a discount bundling case. Moreover, the schedule proposed by Ortho/J&J provides insufficient time for Amgen to comply and to conduct its own discovery, which is typically extensive in cases such as this one.

A. There Is No Case Law Supporting The Relief Ortho/J&J Seeks

1. Analogous Cases Have Not Been Subject To A Preliminary Injunction

To Amgen's knowledge, no court has ever issued a preliminary injunction to reverse the implementation of a multi-product discount arrangement. *See, e.g., Masimo Corp. v. Tyco Health Care, et al.*, 2:02-cv-04770 (C.D. Cal. Filed May 22, 2002) (involving discounts across multiple products, including defendant's pulse oximeters); *LePage's, Inc. v. 3M*, No. 97-3983, 2000 U.S. Dist. LEXIS 3087 (E.D. Pa. Mar. 14, 2000) (multi-product discount on six of defendant's product lines); *SmithKline v. Eli Lilly & Co.*, 427 F. Supp. 1089 (E.D. Pa. 1976) (multi-product discount on defendant's five cephalosporin products); *Ortho Diagnostic Sys., Inc.*, 822 F. Supp. 145 (No. 93-CV-2656) (denying motion for preliminary injunction where multi-product discount involved at least four of defendant's five blood tests); *Kinetic Concepts, Inc. v. Hillenbrand Indus., Inc.*, 262 F. Supp. 2d 722 (Docket No. 95-CV-755) (multi-product discounts on hospital beds with rental therapy equipment).

Ortho/J&J cites no case involving a pricing arrangement similar to Amgen's in which the court issued a preliminary injunction. Many of Ortho/J&J's cases involve completely different issues of law. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100 (1969) (patent misuse and conspiracy to restrain trade); *Highmark, Inc. v. UPMC Health Plan, Inc.*, 276 F.3d 160 (3d Cir. 2001) (deceptive advertising); *ACLU v. Reno*, 217 F.3d 162 (3d Cir. 2000) (Child Online Protection Act); *In re Arthur Treacher's Franchisee Litig.*, 689 F.2d 1137 (3d Cir. 1982) (trademark infringement, unfair competition, and breach of contract); *ECRI v. McGraw-Hill, Inc.*, 809 F.2d 223 (3d Cir. 1987) (breach of contract); *Alcatel Space, S.A. v. Loral Space & Communs. Ltd.*, 154 F. Supp. 2d 570 (S.D.N.Y. 2001) (breach of contract).

In others, the preliminary injunction sought by plaintiff was denied. *See Allen-Myland, Inc. v. Int'l Bus. Machines Corp.*, 33 F.3d 194 (3d Cir. 1994) (preliminary injunction denied in action involving defendant's net pricing policy); *Cent. Jersey Freightliner, Inc.*, 987 F. Supp. 289 (preliminary injunction denied where plaintiff sought to enjoin termination of franchise agreements); *Allis-Chalmers Mfg. Co. v. White Consol. Indus., Inc.*, 414 F.2d 506 (3d Cir. 1969) (preliminary injunction denied where plaintiff sought to enjoin defendant from purchasing any more stock).

2. Cases Cited by Ortho/J&J Where Expedited Discovery Was Ordered Are Not Analogous To The Present Case

Furthermore, the cases cited by Ortho/J&J to support its claim for expedited discovery do not involve similarly complex factual or legal issues. *See TKR Cable Co. v. Cable City Corp.*, 267 F.3d 196 (3d Cir. 2001) (piracy of cable transmissions); *Acierno v. Mitchell*, 6 F.3d 970 (3d Cir. 1993) (zoning dispute); *Glaxosmithkline Consumer Healthcare, L.P. v. Merix Pharm. Corp.*, No. Civ. 05-898, 2005 WL 2230318 (D.N.J. Sept. 13, 2005) (false advertising claim filed after challenge brought before the Better Business Bureau and appeal brought before the National Advertising Review Board and after three months of expedited discovery); *Barre-National, Inc. v. Doshi*, No. Civ. 88-1847, 1988 WL 36335 (D.N.J. Apr. 18, 1988) (breach of contract, tortious interference, and misappropriation of trade secrets where employee hired by competitor); *Capital City Publ'g Co. v. Trenton Times Corp.*, 575 F. Supp. 1339, 1342 (D.N.J. 1983) (conspiracy case in which defendant voluntarily agreed to cease complained-of activity).

B. Ortho/J&J's Proposed Schedule Provides Insufficient Time To Complete Discovery Necessary To Properly Adjudicate Ortho/J&J's Claims

1. Ortho/J&J's Proposed Schedule Allows Too Little Time For Amgen to Fully Comply with Ortho/J&J's Discovery Requests

The discovery schedule proposed by Ortho/J&J provides insufficient time for Amgen adequately to respond to Ortho/J&J's requests. Ortho/J&J makes at least 23 distinct document requests, requests depositions for several individuals, and requests 30(b)(6) depositions of Amgen and a third party on 19 detailed subjects. Ortho/J&J requests that all these events take place within three weeks.

2. Ortho/J&J's Proposed Schedule Allows Too Little Time For Amgen Properly To Conduct Its Own Discovery

Just as Ortho/J&J claims it requires substantial discovery to support its preliminary injunction motion, Amgen would require at least the same amount of discovery to oppose that motion. Section C, *infra*, summarizes the discovery that would be required by Amgen to mount an adequate defense against Ortho/J&J's claims.

3. Ortho/J&J's Proposed Schedule Provides Too Little Time To Generate An Adequate Economic Analysis

In addition, Amgen would require significant discovery from industry and economic experts regarding market definition, the effect of Amgen's discount arrangements, the effect of the evolving reimbursement regulations, and other legal and factual issues. These experts typically require months to research the relevant market conditions and provide an accurate and professional analysis. Discovery from these sources is typical in major antitrust cases such as this.

C. Full Discovery Is Necessary To Appropriately Resolve These Complex Legal and Factual Issues

Antitrust cases involving similarly complex factual and legal issues often require extensive discovery in order to fully explore those issues. The *LePage's* case, for example, went to trial more than two years after the filing of the complaint. No. 97-3983, 2000 U.S. Dist. LEXIS 3087 (E.D. Pa. March 14, 2000). A jury trial in the *KCI v. Hillenbrand* case began more than seven years after the filing of the complaint. See *Kinetic Concepts*, 262 F. Supp. 2d 722 (Docket No. 95-CV-755). The *Masimo Corp. v. Tyco Health Care* case went to trial nearly three years after filing of the complaint. See No. 02-CV-04770 (C.D. Cal. 2002). The *Ortho Diagnostic Systems v. Abbott Laboratories* case, in which Ortho was denied its motion for preliminary injunction, was ultimately scheduled to go to trial more than three years after filing of the complaint until the case settled just prior to the trial date. 920 F. Supp. 455 (S.D.N.Y. 1993) (Docket No. 93-CV-02656).

In this case, Ortho/J&J's claims make clear the extent to which discovery is needed by both sides to provide a full record upon which this Court can decide:

- ***Discovery to demonstrate economically viable options for oncology clinics.*** Amgen will need to take discovery, both from Ortho/J&J and others, to demonstrate that oncology clinics have various economically viable product mix and purchasing options available to them.
- ***Discovery of Ortho/J&J's ability to lower prices.*** Amgen will need to take full discovery of Ortho/J&J's cost structure and profit margins for Procrit®. Amgen also will need to take discovery of what measure of cost Ortho/J&J is asserting it might, eventually, need to price below in order to compete. Pl. Compl. ¶ 69 (referencing an undefined "true measure of cost in the pharmaceutical industry").
- ***Discovery to reveal Ortho/J&J's own bundled discount practices.*** Amgen believes that Ortho/J&J, and/or other J&J subsidiaries, has offered discounts to Procrit customers based on those customers' purchase of products other than Procrit. Amgen will take discovery regarding Ortho/J&J's own bundled discounting activities.
- ***Discovery to understand Ortho/J&J's refusal to lower its prices on a reimbursement-based theory.*** Amgen will need discovery to understand Ortho/J&J's so-called "price

spiral” theory, which references various elements of Procrit’s® ASP, including sales to: oncology clinics, hospitals, nephrology clinics, long term care facilities, and retail. Pl. Compl. ¶ 58. Amgen will need detailed discovery to determine if Ortho/J&J could have discounted and competed, but instead has chosen to try to keep Amgen from lowering prices to consumers so J&J can continue to earn high profits on Procrit®. In particular, Amgen will need discovery on whether, and how much, Ortho/J&J will reduce the price of Procrit® to compete with Amgen’s lower pricing if Ortho/J&J is not able to have the Court raise Amgen’s prices through an injunction.

- ***Discovery of Ortho/J&J ‘s competitive practices and claims of lower profits.*** Amgen will need to take discovery on the causes for Ortho/J&J’s alleged reduced revenues, including actions, if any, it has taken to compete more or less aggressively over that time period. Amgen will also take discovery from Ortho/J&J regarding other factors, such as less favorable dosing regimen for Procrit®, that may have contributed to that alleged loss of share.
- ***Discovery of Ortho/J&J’s planned uses of Procrit®.*** Amgen will need to take discovery regarding Ortho/J&J’s plans to develop new uses for Procrit® and whether and how Ortho/J&J’s sales of Procrit® to oncology clinics would influence those efforts.

The discovery needed to defend Amgen and to respond to Ortho/J&J’s claims will require an extensive period of time, which will be determined pursuant to a regular scheduling conference in the Court’s discretion.

CONCLUSION

For all the foregoing reasons, Plaintiff's Motion for Expedited Discovery should be denied.

Respectfully submitted,

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